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A
BOX PATENT
APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: BIPR115639

TRANSMITTAL LETTER

Seattle, Washington 98101

July 13, 2000

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) by Express Mail is the complete patent application of: N. Robert Ward, Jr. and Geoffrey S. Bright, entitled SAMPLING DEVICE WITH SNAP-OFF HEAD AND METHOD OF USE, executed on July 13, 2000.

- X 1. An application consisting of 9 pages of specification and claims and 2 sheets of informal drawings is attached.
- X 2. A newly executed Declaration and Power of Attorney is attached.
- X 3. An Assignment of the invention to International BioProducts, Inc. is attached. A Cover Sheet prepared in accordance with 37 C.F.R. § 3.31 is attached to the Assignment. Please record this Assignment in accordance with 37 C.F.R. § 3.11.
- X 4. A filing date in accordance with 37 C.F.R. § 1.10 is requested. The Express Mail Certificate appears below.
- X 5. A Small Entity Statement is attached.

COMPUTATION OF FEE

	Number Filed		Number Extra		Rate		Basic Fee 345.00
Total Claims	17 - 20	=	0	x	9.00	=	0.00
Independent Claims	3 - 3	=	0	x	39.00	=	0.00
Multiple Dependent Claims	-0-		---		130.00		
TOTAL							345.00

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- X 6. Our check No. 118423 in the amount of \$345.00 to cover the total filing fee as computed above.
- X 7. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.18 which may be required during the entire pendency of the application, or credit any overpayment, to Deposit Account No. 03-1740. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application. A copy of this sheet is enclosed.

Please address all further correspondence to:

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Respectfully submitted,

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EXPRESS MAIL CERTIFICATE

"Express Mail" mailing label number: EM069882910US

Date of Deposit: July 13, 2000

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Maria Wood
(Typed or printed name of person mailing paper or fee)

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Applicants: N. Robert Ward, Jr. and
Geoffrey S. Bright

Attorney Docket No. BIPR115639

Filed: Concurrently herewith

Title: SAMPLING DEVICE WITH SNAP-OFF HEAD AND METHOD OF USE

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. §§ 1.9(F) AND 1.27(C)) - SMALL BUSINESS CONCERN**

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below:

Name of Concern International BioProducts Incorporated

Address of Concern 21312 30th Avenue Southeast

Bothell, Washington, 98021

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 C.F.R. §§ 121.3-18, and reproduced in 37 C.F.R. § 1.9(d), for purposes of paying reduced fees under 35 U.S.C. §§ 41(a) and (b) in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled SAMPLING DEVICE WITH SNAP-OFF HEAD AND METHOD OF USE by inventors N. Robert Ward, Jr. and Debra K. Cory, described in the specification filed herewith.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. § 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. § 1.9(d) or a nonprofit organization under 37 C.F.R. § 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 C.F.R. § 1.27). NONE

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. § 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful, false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: N. Robert Ward Jr.

Title of Person Other Than Owner: President

Address of Person Signing: 21312 30th Avenue Southeast, Bothell, Washington 98021

Signature: 

Date: 7/12/00

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SAMPLING DEVICE WITH SNAP-OFF HEAD AND METHOD OF USE

Field of the Invention

5 The present invention relates to applicator devices, and more particularly to a sampling device especially suited for use in sterile collection and having an applicator end of absorbent material.

Background of the Invention

10 In the field of sterile collection, it is known to use swabs made of cotton, dacron or alginate to take microbiological samples. Such swabs usually include an swab stick handle that is relatively thin and somewhat bendable. After sampling, the swab is placed into a sterile test tube, plastic container, or other collection bag for transportation back to the laboratory and for later processing.

15 While this approach has been successful for the collection of clinical samples (e.g. throat swabs), it is less than ideal for collection of samples from floors, equipment surfaces and drains in an industrial setting, such as a food production plant. A first disadvantage is that known swabs are best suited for small sampling areas, such as a throat or body wound. Industrial surfaces are generally much larger. To account for the larger sample surface, some industrial sampling procedures use a sterile sponge that the analyst rubs across the sampling surface. The sampling sponge is held by a gloved hand or, sometimes, by sterile forceps. These sponges are
20 effective for larger surfaces, but are susceptible to mishandling by the analyst, resulting in inaccurate results from accidental contamination of the sample.

A second disadvantage is microorganisms that colonize industrial surfaces can form strong attachments, called "biofilms", that require a certain amount of scrubbing in order to release them from their underlying surface. Consequently, it is

difficult to lift this biofilm by scrubbing a wide surface area using a relatively small swab having a bendable handle.

5 A third drawback is that an analyst taking a sample may contaminate the sample by introducing matter from the analyst's hand onto the applicator stick (the area held by the analyst). To address issues of purity, alternative swab devices have been developed for collection of clinical samples whereby a cap holds the swab and the analyst only holds the cap. The cap also serves to seal the transport container. Such an approach does improve the purity of the sample, but unfortunately requires extra plastic and an additional manufacturing step to produce.

10 In addition to the above problems, a large accumulation of collection bags with sample swabs located therein is cumbersome to transport and store. Overcrowding of the bags and various types of mishandling can occur in which the swab inadvertently punctures the collection bag and, consequently, compromises the quality of the sampled content.

15 Thus, a need exists for an improved surface sampling device for use in sterile collection. The ideal sampling device would be easy to use and cause minimal opportunity for accidental contamination by the analyst. The device would also be effective at sampling large areas and be capable of lifting an attached biofilm through the scrubbing action by the analyst. Finally, after the sample is taken, the sampling
20 device can be transported back to the laboratory without puncturing the bag used to transport the device. The present invention is directed to fulfilling these needs and others as described below.

Summary of the Invention

25 In accordance with the present invention, a sampling device is provided having an elongate handle with a distal paddle head. An absorbent material is positioned about the paddle head, and a score line is located along the handle at a location adjacent the padded head. During use, the paddle head and absorbent material are snapped off of the elongate handle.

30 In accordance with other aspects of this invention, the absorbent material is sized to encompass the exposed score line after the paddle head is snapped from the handle. In one embodiment, the absorbent material is a single piece of generally rectangular absorbent material folded about the paddle head and adhered thereto. The head includes a distal edge and the absorbent material is folded about the distal edge. The handle and paddle head are integrally formed of a material such as
35 polystyrene, polycarbonate, polypropylene, polyethylene, or ABS.

In one embodiment, the paddle head is approximately 0.2 cm thick, 3.2 cm wide, and 3.2 cm long; and the absorbent material is approximately 1.5 cm thick, 4.0 cm wide, and 8.0 cm long. The absorbent material overhangs the score line by an amount in the range of about 0.5 cm to about 1.0 cm, and is formed of a material
5 such as cellulose, polyurethane, polyester, or gauze.

Brief Description of the Drawings

The foregoing aspects and many of the attendant advantages of this invention will become more readily appreciated as the same become better understood by reference to the following detailed description, when taken in conjunction with the
10 accompanying drawings, wherein:

FIGURE 1 is a perspective view of one embodiment of a sampling device formed in accordance with the present invention;

FIGURE 2 is a side elevation view of the embodiment of FIGURE 1; and

FIGURE 3 is a perspective view of a preferred method of using the sampling
15 device of FIGURE 1.

Detailed Description of the Preferred Embodiment

The present invention is a sampling device 10 for absorbing industrial chemicals, medical samples, waste material, and other such matter to be collected, transported, and later analyzed.

Referring to FIGURE 1, the sampling device 10 includes an elongate handle 12 with a distal paddle head 14. The head 14 is generally flat with rounded corners, and of a width greater than the width of the handle 12. In one embodiment, the handle 12 and paddle head 14 are integrally formed of a rigid material, such as polystyrene, polycarbonate, polypropylene, polyethylene, and ABS (Acrylonitrile-
20 Butadiene-Styrene) The handle of FIGURE 1 includes a thumb stop 16 provided to improve the user's connection with the handle. The thumb stop 16 is located approximately mid-way along the handle length. Other types of grip-enhancing features may be used, e.g., roughened surfaces, finger indentations, etc.

A score line 18 is located along the handle at a location adjacent the padded
30 head. A preferred score line includes first and second ends that are recessed inward. The handle portions adjacent these recessed ends are rounded so that when the paddle head is broken off (as described below) there are no exposed sharp corners on either of the resulting handle or paddle head pieces. This arrangement reduces the risk of a user cutting themselves on the handle portion after breaking it from the paddle, and

reduces the chances of a sharp corner on the paddle head poking a hole in the sterile sample bag and possibly compromising the sterility of the sample.

Referring to FIGURES 1 and 2, an absorbent material 20 is placed about the paddle head in such a manner as to encompass the score line. In one embodiment, this is accomplished by sizing the absorbent material sufficiently large so as to extend past the score line by an amount X. See FIGURE 2. The absorbent material is formed of an absorbent material, such as cellulose, polyurethane, polyester, or gauze.

In the embodiment of FIGURES 1-3, the absorbent material 20 is a single piece of generally rectangular absorbent material folded about the paddle head 14 and adhered thereto. The fold line of the material is located along the distal edge of the paddle head. The absorbent material overhangs the score line by an amount in the range of about 0.5 cm to about 1.0 cm. The paddle head 14 is approximately 0.2 cm thick, 3.2 cm wide, and 3.2 cm long; and the absorbent material is approximately 1.5 cm thick, 4.0 cm wide, and 8.0 cm long. Other arrangements are possible. For example, the fold line may be located along a side edge, or the absorbent material may be formed as a sock that slips over the paddle head.

Referring to FIGURE 3, during use, a user collects the specific matter (such as microorganisms) into the absorbent material. The head and saturated material is then placed in a sterile collection bag 22 or the like. In known sterile collection bags, a flexible plastic bag body 24 includes an upper opening 26 into which the sampling device may be inserted. The user grabs the paddle head (as wrapped by the bag body) and quickly snaps the head from the handle along the score line. The score line permits this to occur with relatively little effort. The user then extracts the handle, thus leaving only the paddle head and saturated absorbent material in the sterile collection bag. This arrangement allows a user to collect a surface sample via swabbing, and deposit the sample in a sterile flexible wall container without ever directly touching the absorbent material. In one embodiment, the handle includes a thumb stop located approximately mid-way along the handle. During use, the paddle head is inserted into the sample bag up to the thumb stop.

As will be appreciated, once the handle portion is snapped away from the paddle head, the oversized absorbent material surrounds the rough edges that may exist at the score line tear points along the detached head and, thus, successfully protects the sterile collection bag from puncture. In addition, because the handle is

While the preferred embodiment of the invention has been illustrated and described, it will be appreciated that various changes can be made therein without departing from the spirit and scope of the invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A sampling device comprising:
 - (a) an elongate handle with a distal paddle head;
 - (b) an absorbent material placed about the paddle head; and
 - (c) a score line located across the handle at a location adjacent the padded head; wherein during use, the paddle head and absorbent material may be snapped off of the elongate handle,
2. The sampling device according to Claim 1, wherein the absorbent material is sized sufficiently large to encompass the exposed score line after the paddle head is snapped from the handle.
3. The sampling device according to Claim 1, wherein the absorbent material is a single piece of generally rectangular absorbent material folded about the paddle head and adhered thereto.
4. The sampling device according to Claim 3, wherein the head includes a distal edge and the absorbent material is folded about the distal edge.
5. The sampling device according to Claim 4, wherein the paddle head is approximately 0.2 cm thick, 3.2 cm wide, and 3.2 cm long; and wherein the absorbent material is approximately 1.5 cm thick, 4.0 cm wide, and 8.0 cm long.
6. The sampling device according to Claim 1, wherein the absorbent material overhangs the score line by an amount in the range of about 0.5 cm to about 1.0 cm.
7. The sampling device according to Claim 1, wherein the absorbent material is formed of at least one of cellulose, polyurethane, polyester, and gauze .
8. The sampling device according to Claim 1, wherein the handle and paddle head are integrally formed.
9. The sampling device according to Claim 1, wherein the handle and paddle head are formed of at least one of polystyrene, polycarbonate, polypropylene, and acrylonitrile-butadiene-styrene.

10. The sampling device according to Claim 1, wherein the handle includes a thumb stop.

11. The sampling device according to Claim 1, wherein the score line ends are recessed from the edges of the handle and wherein the portions of the handle adjacent the score line ends are rounded.

12. A sampling device comprising:

(a) an elongate handle with an integrally-formed distal paddle head, the head includes an outer edge;

(b) a single piece of generally rectangular absorbent material folded about the paddle head outer edge and adhered thereto; and

(c) a score line located across the handle at a location adjacent the padded head; the score line including first and second ends recessed from the edge of the handle; the portions of the handle adjacent the score line ends being rounded; the absorbent material overhanging the score line by an amount in the range of about 0.5 cm to about 1.0 cm;

wherein during use, the paddle head and absorbent material may be snapped off of the elongate handle, the overhanging portion of the absorbent material encompassing the exposed score line after the paddle head is snapped from the handle.

13. A method of sampling microorganisms, comprising:

(a) wiping a surface with a sampling device having an elongate handle with a distal paddle head, an absorbent material placed about the paddle head, and a score line located across the handle at a location adjacent the padded head;

(b) inserting the paddle head with absorbent material into a flexible-walled sample bag;

(c) grasping the paddle head from the exterior of the sample bag;

(d) breaking the handle from the paddle head at the score line; and

(e) removing the handle from the bag.

14. The method according to Claim 13, wherein the handle includes a thumb stop located approximately mid-way along the handle; and wherein during use, the paddle head is inserted into the sample bag up to the thumb stop.

16. The method according to Claim 13, wherein the absorbent material is sized sufficiently large to encompass the exposed score line after the paddle head is broken from the handle.

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Abstract of the Disclosure

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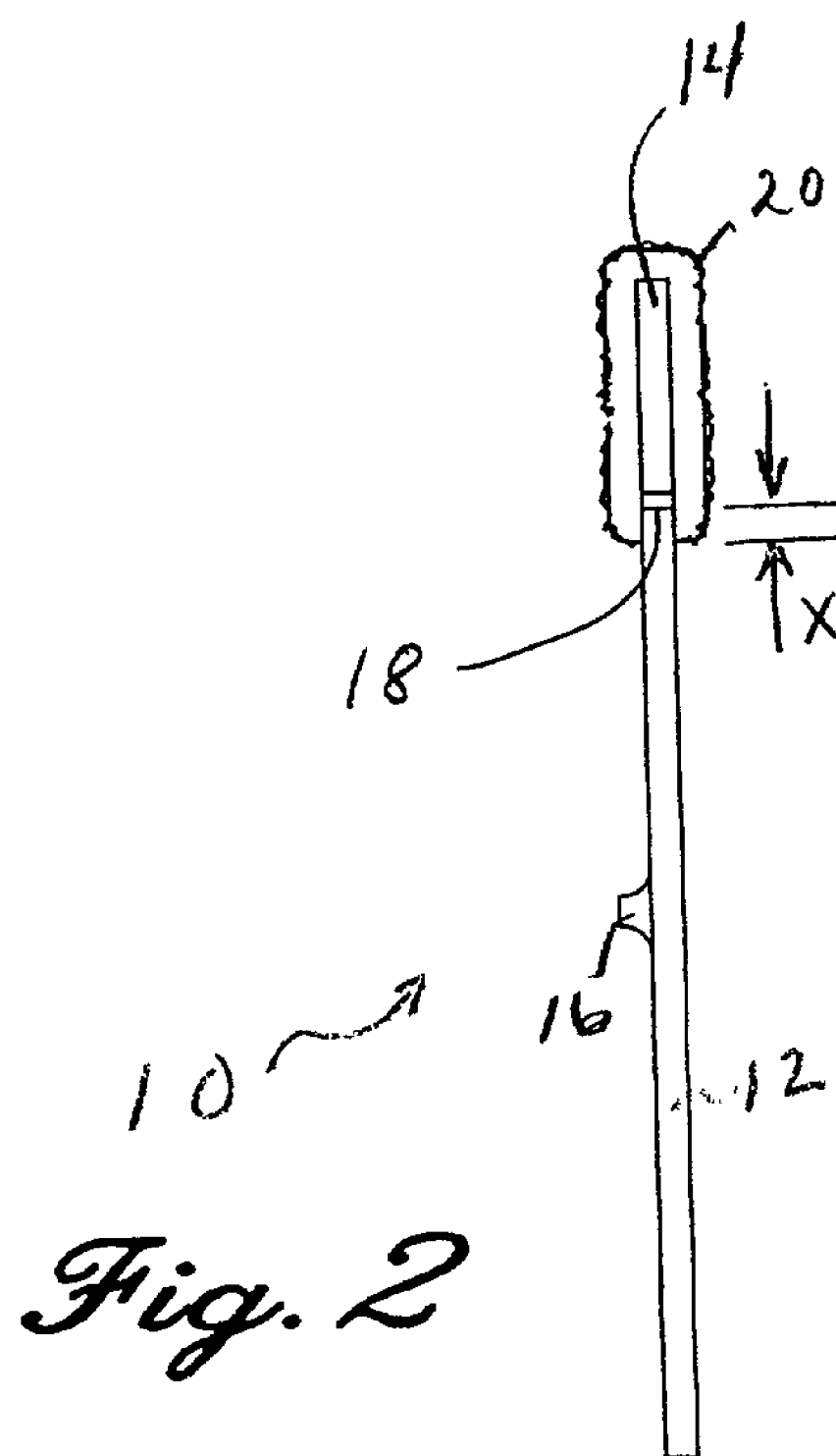
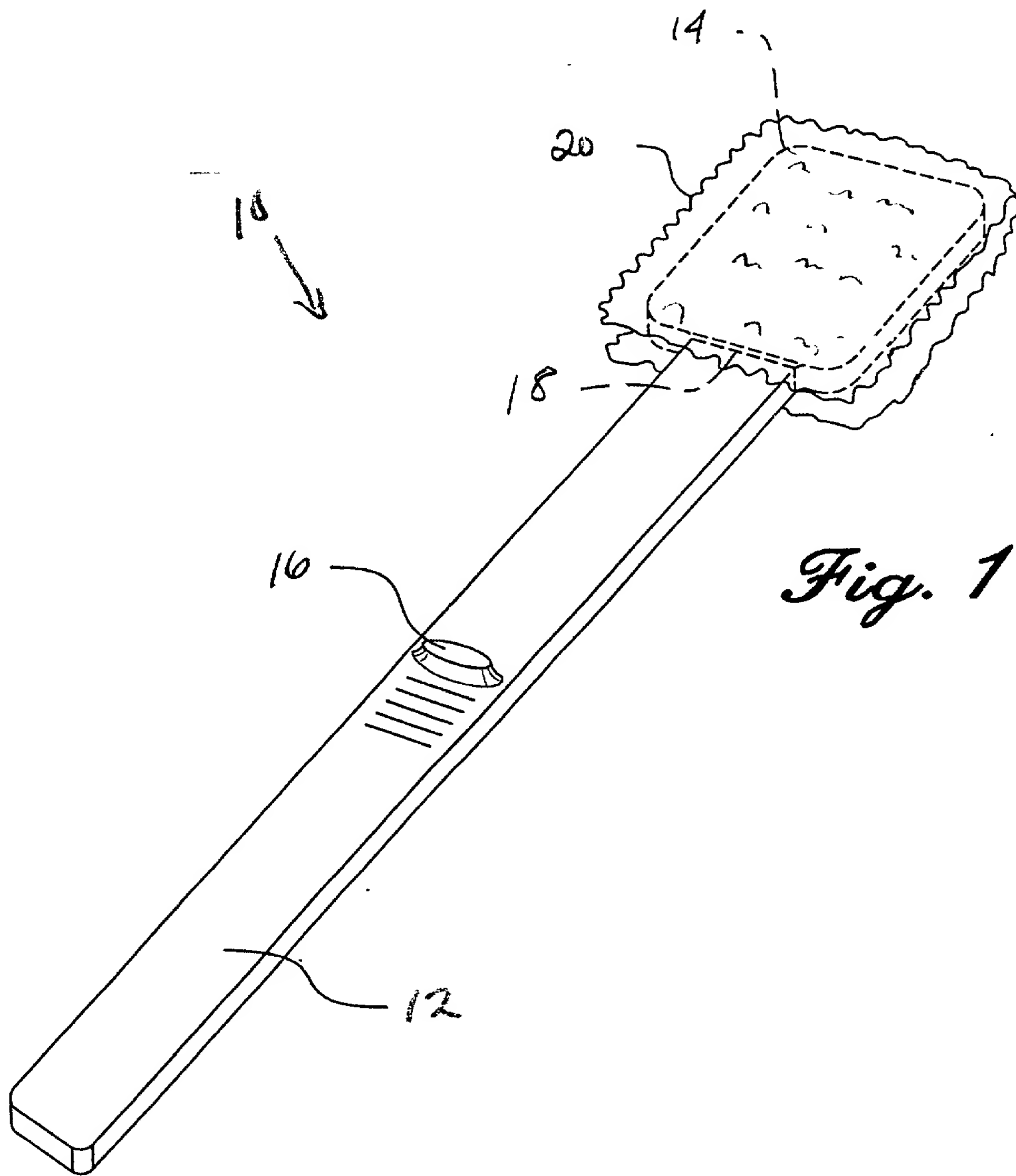
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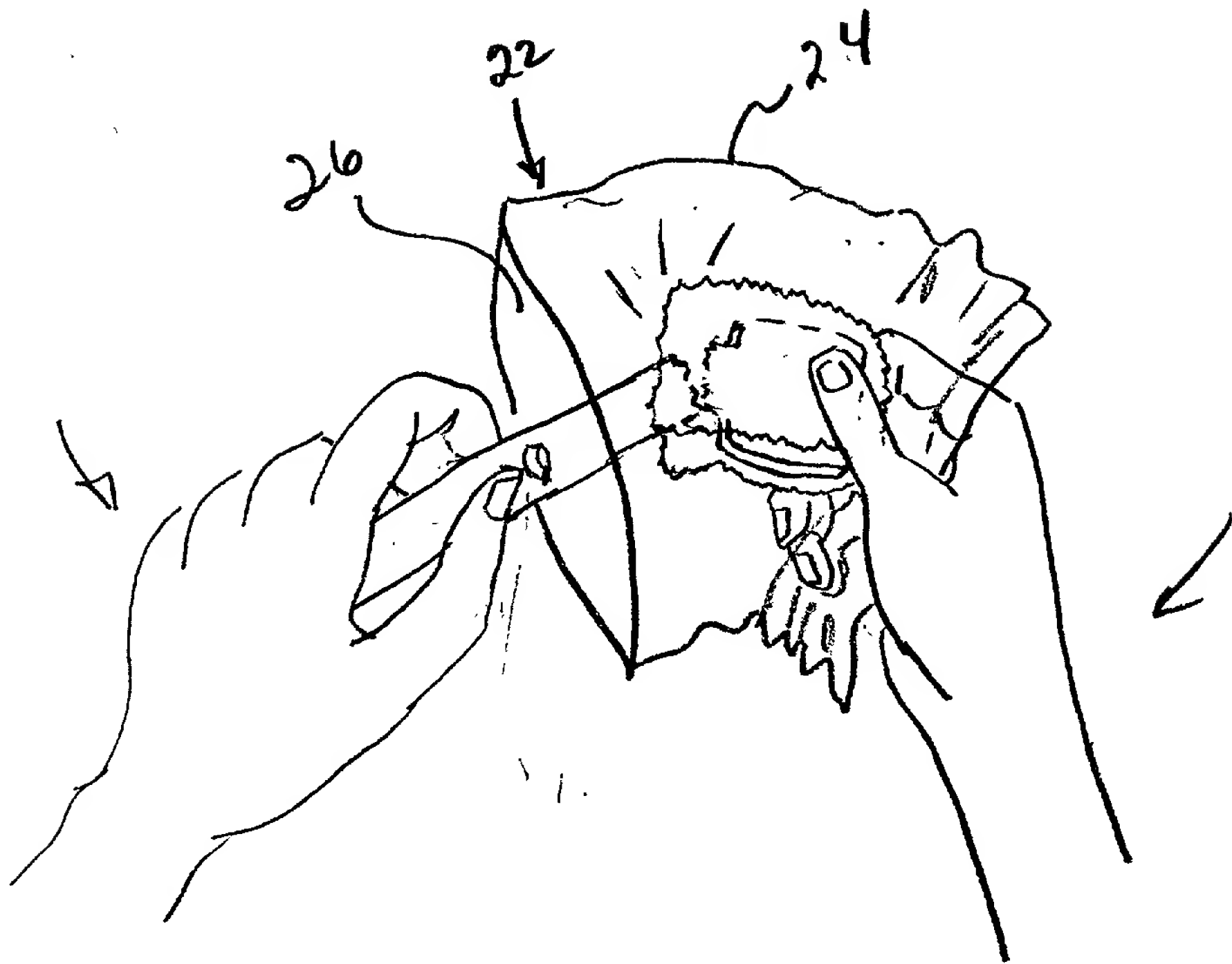


FIG. 3

03643636-02100

Attorney Docket No.: BIPR115639

**COMBINED DECLARATION AND POWER OF ATTORNEY
IN PATENT APPLICATION**

As a below-named inventor, I hereby declare that:

my residence, post office address and citizenship are as stated below next to my name;

I believe that I am an original, first and joint inventor of the subject matter that is claimed and for which patent is sought on the invention entitled **SAMPLING DEVICE WITH SNAP-OFF HEAD AND METHOD OF USE**, the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(c), of any foreign application(s) for patent listed below and have also identified below, any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: **NONE**

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(d), of any inventor's certificate listed below. I declare that, upon investigation, I am satisfied that to the best of my knowledge, when filing the application for the inventor's certificate I had the option to file an application for either a patent or an inventor's certificate as to the subject matter of the identified claim or claims forming the basis for the claim of priority: **NONE**

I hereby claim the benefit under Title 35, United States Code, Section 119(e), of any United States provisional application(s) listed below: **NONE**

I hereby claim the benefit under Title 35, United States Code, Section 120, of any United States application(s) or PCT international application(s) designating the United States listed below, and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a), which occurred between the filing date of the prior application and the national or PCT international filing date of this application: **NONE**

I hereby appoint the following attorneys and/or agents to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith: Bruce E. O'Connor, Reg. No. 24,849; Lee E. Johnson, Reg. No. 22,946; Gary S. Kindness, Reg. No. 22,178; James W. Anable, Reg. No. 26,827; James R. Uhler, Reg. No. 25,096; Jerald E. Nagaa, Reg. No. 29,418; Dennis K. Shelton, Reg. No. 26,997; Jeffrey M. Sakol, Reg. No. 32,059; Ward Brown, Reg. No. 28,400; Robert J. Carlson, Reg.

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I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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